

REMARKS

Reconsideration is respectfully requested. As further elucidated below, the references cited in the present Action do not meet the requirements of either Section 102 or 103 because they do not describe layered drug delivery films that contain plasticizer. No claim amendments have been made. Consequently, claims 1-10, 12, 13, 15-18, 33, and 34 are currently under consideration.

Examiner Interview

Applicants again wish to thank the Examiner for the telephonic interview of July 16, 2002. Applicants respectfully remind the Examiner that during the interview it was discussed that a limitation excluding plasticizer would overcome the prior art rejections.

Claim Rejections

Claims 1-6, 9, 12, 15, and 17-18 Under 35 U.S.C. § 102(b)

Claims 1-6, 9, 12, 15, and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,765,983 to Takayanagi et al. In particular, the Office Action states:

“Takayanagi et al. teach a medical tape for oral mucosa comprising a support layer and a medical layer composed of water-soluble polymer (abstract). PVP, sodium polyacrylate, and carboxyl cellulose are specified (column methyl 2 lines 61-64). A second polymer, hydroxypropyl cellulose, is specified (column 3 lines 61-64). The medicament layer may be comprised of two or more layers (column 3 line 2). Methylcellulose is specified (column 2 lines 65-66). Dissolution may be varied by proper section of polymers (column 3, lines 29-33) anti-inflammatory steroids are disclosed (column 2 lines 48-53). A 20 um thickness is specified (column 3, lines 15-16).”

Applicants submit that claims 1-6, 9, 12, 15, and 17-18 are not anticipated under Section 102. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See* MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Independent claims 1 and 17 recite a layered flexible film that includes an adhesive layer and a non-adhesive layer. The adhesive layer is made from a film-forming polymer and a bioadhesive polymer. The adhesive layer is free of plasticizer.

Takayanagi et al. teaches the use of plasticizers (referred to as "softening agents") in both the medicament layer and the support layer at column 4 lines 5-11, and in all the Examples. Commonly used plasticizers include, but are not limited to, alkyl-glycols such as propylene glycol, polyethylene glycols, and stearate or esters of glycerol. The cited reference incorporates propylene glycol, glycerin, or polyethylene glycol 400, among other plasticizers, when preparing each tape layer. As mentioned above, the claimed invention is free of plasticizer. Accordingly, Takayanagi et al. does not describe an adhesive tape that does not have a plasticizer.

Based on the foregoing, Takayanagi et al. does not describe or suggest all the claim limitations required under 35 U.S.C. § 102(b). Withdrawal of the rejection of claims 1 and 17 is respectfully requested.

Since claims 2-6, 9, 12, and 15 depend from claim 1, and claim 18 from claim 17, they also include the feature of being "free of plasticizer." Consequently, they are also not anticipated by Takayanagi et al., and withdrawal of the rejection of these claims is respectfully requested.

Claims 1-9, 12, 17-19, and 34 Under 35 U.S.C. § 103(a)

Claims 1-9, 12, 17-19, and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,765,983 to Takayanagi et al. in view of WO 95/05416 and EPA 250187. In particular, the Office Action states:

"WO '416 teaches overlaying an adhesive layer to prevent leakage of active from edges (page 30 lines 16-24)."

EPA '187 teaches and intra-oral film (Title). Flavors are disclosed as customary (page 4, lines 412-43)."

"It would have been obvious to one of ordinary skill to overlay an adhesive layer in Takayanagi et al. to achieve the beneficial effect

of preventing leakage of active form edges in view of WO '416 and to add a flavor as a customary additive in intra-oral films in view of EPA '187."

Applicants submit that a *prima facie* case of obviousness has not been properly established. To establish a *prima facie* case of obviousness, three basic criteria must be met, one of which the prior art reference (or references combined) must teach or suggest all the claim limitations. See MPEP 2143.

As discussed above, Takayanagi et al. does not teach or suggest an adhesive tape that is free of plasticizer. WO '416 describes a laminated device for the controlled release of a substance that includes a plasticizer to increase its tack. Furthermore, EPA '187 is a medicament containing film having a bioadhesive layer that contains 2-10% of a plasticizer. Thus, when the teachings of Takayanagi et al., WO '416, and EPA '187 are combined, they do not teach a pharmaceutical carrier device having all the limitations of the independent claims (1, 17, and 34).

Accordingly, a *prima facie* case of obviousness has not been properly established. Withdrawal of the rejection of claims 1-9, 12, 15, 17-18, and 34 under 35 U.S.C. § 103(a) is respectfully requested.

SUMMARY

Applicants have responded to each matter of substance raised in this Office Action and believe that the case is in condition for allowance. Should the Examiner have any requests, questions, or suggestions, he is invited to contact the Applicants' representative at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: February 26, 2003

By:



Lisa A. Amfi

Registration No. 48,199

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5747
Facsimile: (650) 494-0792